Remarks

In the Office Action the Examiner rejected claims 1-25, 28, 49-54, 65-71 and 73-76 under 35 U.S.C. 103(a), as being unpatentable over Lennox (US Patent # 6,159,143) in view of Candelaria et al (US Patent # 6,497,646). Applicants respectfully disagrees, and have amended the claims to further clarify their invention.

Lennox teaches a medical device, shown in Fig. 2, which comprises an integral unit strip with alternating radioactive sections and adjunctive therapeutic segments, and a further embodiment, shown in Fig. 3, which comprises an elongated member including adjunctive therapeutic with spaced break off lines. The elongated member can be trimmed to create custom spacers and the spaced break off lines are used for indicating length and facilitating cutting or breaking off segments of pre-determined size. The diameter of the elongated member can be made to accommodate the diameter of a seed placement device (Lennox Col. 4, lns. 14-25).

The devices taught by Lennox are materially different from the devices claimed in the instant application. In the instant devices, spacers (or therapeutic segments acting as spacers) and/or seed placement devices are not needed, since the seeds are held in place at the proper intervals by the material that forms the elongated member itself. Also, time-consuming and potentially inaccurate customization of the strands by the treating physician is avoided by the instant invention, because the seeds can be precisely spaced at any desired interval during manufacture of the elongated member.

In the discussion of these embodiments, Lennox did not consider the importance of having the elongated implants be flexible, but focused on the placement and customization of the length of the spacers. The teachings of Lennox, therefore, taught away from the instant invention by calling for rigid implants. It is known that as the tissue or glands shrink back to pre-operative size and as the tissue recedes, a rigid elongated implant does not move with the tissue, but remain stationary relative to the patient. The final location relative to the tumor is thus not maintained, and the dosage of the radioactive seeds would not meet the pre-operative therapy plan. (*See* Application, paragraph [0010].)

The second reference, Candelaria et al, teaches a device that has substantially the same profile as an intravascular radiotherapy source ribbon assembly, but rather than containing radioactive materials, the assembly comprises the same substrate as well as markers of differing radiopacity to map out the area under treatment. The device, termed an "unidummy intravascular radiotherapy source ribbon assembly," comprises a container defining a cavity, a core disposed within the cavity, the core comprising at least one section having a first radiopacity and one or more sections having a second radiopacity. (Candelaria, abstract. *See also* Independent claims 1 and 9). This unidummy ribbon assembly has substantially the same profile and characteristics as a "hot" or radioactive intravascular radiotherapy source ribbon assembly, and is utilized to ensure that the path through the vasculature or other pathway in the body is free of obstructions or open to the site of radiation delivery without exposing the patient to unnecessary radiation. (Candelaria, col. 4, lns.1-15).

The structure disclosed above is different from the structure of the instant invention in material ways. Notably, the structure of Candelaria requires the use of spacers to properly position seeds within a tubular container. The spacers and the seeds are both removably mounted within said container. Candelaria, Col. 6, lns 4-19. In the instant invention, spacers or a separate container defining a cavity are not needed.

Spacers are an integral part of both the Lennox and Cardelaria inventions. Without using spacers, there is no mechanism provided that would position the seeds in the desired intervals. Both references, therefore, do not teach or render obvious the instant device, which uses a polymeric material to encapsulate and position the seeds, and forms the elongated member at the same time. In the preferred embodiment of the instant invention, the elongated member has a constant diameter substantially similar to the encapsulated seeds, giving the member the desired characteristics of being axially rigid and radially flexible.

Candelaria calls for the container to be "preferably flexible enough to navigate through narrow and/or tortuous pathways and stiff enough to traverse the same narrow and/or tortuous pathways." The preferred embodiment calls for the use of Nylon® to form the container. (Candelaria et al col. 5, lns 35-38). This is a different consideration from Applicants' claimed invention, which calls for an elongated member that is "sufficiently rigid axially to allow expulsion of the member while maintaining the spacing between seeds, and

that the member be flexible and pliable enough to move with the tissue as the tissue shrinks back to pre-operative size." Application, paragraph [0018] (emphasis added). "The longitudinal flexibility of the elongated member allows locational accuracy to be maintained as the gland shrinks to pre-procedural size, as the swelling that occurs during tissue disruption and needle manipulation recedes." Application, paragraph [0051].

As Candelaria does not teach or discuss the benefits of having its implant possess the quality of being able to move with the tissue as it shrinks in order to maintain proper placement of the seeds, it cannot be argued that the *flexibility* called for in Candelaria (*i.e.*, in order to navigate the pathway) would teach or render obvious the novel features of the claimed invention.

Additional novel features and teachings of the instant invention, including having the seeds contain a drug or hormone and being bio-absorbable, which bio-absorbable polymers are useable, the exact number of days over which the bio-absorbable elements will be absorbed, the use of echogenic materials, the durometer range of the elongated member, steam sterilizabilty, and the use of air bubbles to make the polymer echogenic are not taught by either Lennox and Candelaria,(Office Action, pages 4-5).

It is clear that Lennox and Candelaria et al, either taken together, separately or when combined with the prior art, do not teach nor render obvious applicants' invention. Accordingly, applicants have amended and added new claims to further clarify their invention, and respectfully request reconsideration of the application and the claims.

Additional references cited by the Examiner but not relied upon have been reviewed, but are not believed to render the claims unpatentable, either singly or in combination.

In light of the above, it is respectfully submitted that all of the claims now pending in the subject patent application should be allowable, and a Notice of Allowance is requested. The Examiner is respectfully requested to telephone the undersigned if he can assist in any way in expediting issuance of a patent.

Enclosed is a Petition for Extension of Time under 37 C.F.R. § 1.136 for extending the time to respond up to May 15, 2003.

The Commissioner is authorized to charge any underpayment or credit any overpayment to Deposit Account No. 06-1325 for any matter in connection with this response, including any fee for extension of time, which may be required.

Respectfully submitted,

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